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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,496	12/21/1999	RON WAKSMAN M. D.	WELD-111-DIV	3711

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EXAMINER	
DESANTO, MATTHEW F	

ART UNIT	PAPER NUMBER
3763	17

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/468,496	WAKSMAN M. D. ET AL.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-35,37,42-44 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-35,37,42-44 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 32, 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 32, 33 recite the limitation "the treating element." The examiner would suggest changing "the" to "a".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 48, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Nita (USPN 5,267,954).

Nina discloses a catheter comprising, a first tube having a lumen closed at its distal end and sized to receive the treating element, a second tube in parallel relation to

the first tube and having a lumen open at its distal end and sized to receive a guidewire, and a third tube for receiving first and second tube and having a fluid return lumen in fluid communication with the lumen of the first elongated tube.

Where the distal end of the third tube extends beyond the distal ends of the first and second tubes. Wherein the distal end of the second tube is coterminous with the distal end of the third tube, both which extend beyond the distal end of the first tube. Wherein the lumen of the first tube has an inside diameter less then twice the outside diameter of the treating element. Wherein the first tube includes an internal barrier to block the passage of the treating element out of the first tube, and where the internal barrier has an aperture. (Figures 6, 6b, 10 and entire reference).

6. Claims 29, 32-34, 42, 43, 44, 47, 48, and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrison et al. (USPN 5,554,119).

Harrison et al. discloses a catheter comprising, a first tube (172) having a lumen partially closed at its distal end and sized to receive the treating element, a second tube (32) in parallel relation to the first tube and having a lumen open at its distal end and sized to receive a guidewire, and a third tube (164) for receiving first and second tube and having a fluid return lumen in fluid communication with the lumen of the first elongated tube. (Figure 3B, and entire reference)

Wherein the lumen of the first tube has an inside diameter less then twice the outside diameter of the treating element. Wherein the first tube includes an internal barrier to block the passage of the treating element out of the first tube, and where the internal barrier has an aperture. (Figure 3B and entire reference).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 29-35, 37, 42-44, 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (USPN 5,554,119) as applied above.

At the time of the invention it would have been obvious for one of ordinary skill in the art to modify the invention with regards to the catheter length and shape. It is well known in the catheter and tubing art to modify the length and the diameter (size) of catheters as well as the shape of the catheter. Claims 30, 32, 35, 37 are all routine modification that are well known in the catheter and tubing art. The examiner would also like to state that it would have been an obvious matter of design choice to one skilled in the art to modify the apparatus as taught by Harrison et al. to have the distal end of the catheter as claimed, since applicant has not disclosed any criticality, novelty and/or unexpected results and it appears that the invention would perform equally well with any distal end catheter structure, such as the catheter as taught by Harrison et al.

Response to Arguments

9. Applicant's arguments filed 3/10/04 have been fully considered but they are not persuasive.

10. The applicant argues nothing with respect to Nita and the treating element. The examiner is interpreting anything that can perform a treatment to be a "treatment element," such as fluid. Therefore the prior art reads on the application.

11. The applicant is also discussing intended use with regards to the pressurized fluid, and the treatment element. That argument is given no weight since this is an apparatus claim and the examiner points the applicant to the MPEP section 2114, which deals with intended use and functional language.

12. The 102 Rejection drawn to York is withdrawn, because of the amendments.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 29-34, 35, 37, 42, 43, 44, 47, 48, and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 17, 19, 20, 22, 35, of U. S. Patent No. 5,899,882. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the application are claiming common subject matter, as follows:

a first, second and third tube with a treating element placed in one of the tubes and the only variation is an obvious modification, which is the reinforcing connector. The application has the same principle, but never positive recites the reinforcing connector.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
May 31, 2004

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700